JUN 2 3 2000 K004185

CP Medical

836 NE 24th AVE Portland, OR 97232 **TEL. (503) 232-1555, Fax (503) 230-9993**
P.O. BOX 6724 Portland, OR 97208 **e-mail** CPMEDICAL@aol.com

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1999 and 21CFR 807.92."

Applicant: C.P. Medical
836 N.E. 24th
Portland, OR 97232
Tele: (503) 232-1555
Fax: (503) 230-9993

Contact: Patrick J. Ferguson, (President)
or
Thomas R. Brammer (V.P. Manufacturing)

Date: February 5, 2000

Name of Device:
Common or Usual Name: Polypropylene Nonabsorbable Surgical Sutures
Classification Name: Suture, nonabsorbable, synthetic, Polypropylene

Polypropylene nonabsorbable surgical sutures, USP, manufactured by C.P. Medical are equivalent to Surgilene™ Polypropylene nonabsorbable surgical sutures manufactured by USSC / Davis & Geck.

The Polypropylene sutures manufactured by C.P. Medical and USSC / D&G are monofilament and are dyed blue with Copper Phthalocyanine Blue.

The Polypropylene nonabsorbable surgical sutures USP, are indicated for use in general soft tissue approximation and/or ligation, including use in Cardiovascular, Ophthalmic and Neurological procedures.

Testing of suture diameter, suture length, knot pull tensile strength and needle attachment strength according to methods described in USP 24 demonstrates that C. P. Medical Polypropylene sutures meet or exceed USP specifications and are equivalent in terms of the above parameters to Polypropylene sutures manufactured by USSC / Davis & Geck.

Patrick J. Ferguson, President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2000

Mr. Patrick Ferguson
President
CP Medical
836 N. E. 24th Avenue
Portland, Oregon 97208

Re: K001185
Trade Name: Polypropylene Nonabsorbable Surgical Suture
Regulatory Class: II
Product Code: GAW
Dated: April 11, 2000
Received: April 11, 2000

Dear Mr. Ferguson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Friday, May 31, 1991 (Vol. 56, No. 105, Pages 24684 and 24685). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Polypropylene Nonabsorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

2. This device may not be manufactured from any material other than a long chain polyolefin polymer known as polypropylene. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Polypropylene surgical suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, The Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control Provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4595. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597, or at its internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,

Donna R. Bachner.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number if known K001185

Devise Name Polypropylene Nonabsorbable Surgical Suture USP

Indication for Use:

General soft tissue approximation and/or ligation including use in Cardiovascular, Ophthalmic and Neurological procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001185

Prescription Use: X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 00-00-00)